one day after AstraZeneca fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or submit the notification or report shall not begin to accrue until three business days after AstraZeneca receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that AstraZeneca has failed to comply with any of the obligations described in section X.A. and after determining that Stipulated Penalties are appropriate, OIG shall notify AstraZeneca in writing of: (a) AstraZeneca's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter"). Such Demand Letter shall specifically state the conduct that the OIG contends constitutes the basis for imposing the Stipulated Penalty.

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, AstraZeneca shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.E. In the event AstraZeneca elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until AstraZeneca cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in section VI.

4. *Independence from Material Breach Determination.* Except as set forth in section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that AstraZeneca has materially breached this

CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in section X.D, below.

D. Exclusion for Material Breach of this CIA

1. *Definition of Material Breach.* A material breach of this CIA means:

a. a failure by AstraZeneca to report a Reportable Event and take corrective action as required by Section III.I;

b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in section X.A;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section X.C; or

d. a failure to direct or retain and use the GIA and IRO in accordance with section III.E.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by AstraZeneca constitutes an independent basis for AstraZeneca's exclusion from participation in the Federal health care programs. Upon a determination by OIG that AstraZeneca has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify AstraZeneca of: (a) AstraZeneca's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* AstraZeneca shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. AstraZeneca is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) AstraZeneca has begun to take action to cure the material breach; (ii) AstraZeneca is pursuing such action with due diligence; and (iii) AstraZeneca has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If at the conclusion of the 30-day period, AstraZeneca fails to satisfy the requirements of section X.D.3, OIG may exclude AstraZeneca from participation in the Federal health care programs. OIG will notify AstraZeneca in writing of its determination to exclude AstraZeneca (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, AstraZeneca wishes to apply for reinstatement, AstraZeneca must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights*. Upon OIG's delivery to AstraZeneca of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, AstraZeneca shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review*. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether

AstraZeneca was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. AstraZeneca shall have the burden of proving its full and timely compliance with the obligations at issue and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders AstraZeneca to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless AstraZeneca requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

a. whether AstraZeneca was in material breach of this CIA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30 day period, but that: (i) AstraZeneca had begun to take action to cure the material breach within that period; (ii) AstraZeneca has pursued and is pursuing such action with due diligence; and (iii) AstraZeneca provided to OIG within that period a reasonable timetable for curing the material breach and AstraZeneca has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for AstraZeneca, only after a DAB decision in favor of OIG. AstraZeneca's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude AstraZeneca upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that AstraZeneca may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision

adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. AstraZeneca shall waive its right to notice of such exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of AstraZeneca, AstraZeneca shall be reinstated effective on the date of the original exclusion.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, AstraZeneca and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of AstraZeneca;

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;

D. The undersigned AstraZeneca signatory represents and warrants that he is authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF ASTRAZENECA PHARMACEUTICALS LP AND ASTRAZENECA LP

Glenn Engelmann
Vice President, General Counsel
and Compliance Officer
On behalf of AstraZeneca Pharmaceuticals LP and
AstraZeneca LP

DATE 6/4/03

Kathleen M. Sanzo
John C. Dodds
Morgan, Lewis & Bockius LLP

DATE 6/4/03

ON BEHALF OF ASTRAZENECA PHARMACEUTICALS LP AND ASTRAZENECA LP

Glenn Engelmann
Vice President, General Counsel
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AstraZeneca LP

DATE

Kathleen M. Sanzo

Kathleen M. Sanzo
John C. Dodds
Morgan, Lewis & Bockius LLP

DATE June 4, 2003

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Larry Goldberg

Larry J. Goldberg
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

May 19, 2003
DATE

Attachment A to CIA between AstraZeneca and Office of Inspector General

CERTIFICATION

In accordance with the Corporate Integrity Agreement ("CIA") entered between AstraZeneca Pharmaceuticals LP and AstraZeneca LP (collectively "AstraZeneca") and the OIG, the undersigned hereby certifies that the attached Average Sale Price information has been provided to First DataBank Inc. (and/or other price reporting entity as specified in the CIA); to the State Medicaid programs of those States which executed settlement agreements with AstraZeneca; to the OIG; and to CMS; and that the average sale price has been calculated in accordance with the methodology described generally in the CIA and more specifically in the attached document.

_____ _____

Name
Title

_____

Date

Appendix A to CIA between AstraZeneca and Office of Inspector General

List of Covered Products

1. Cefotan
2. Elavil Injection *
3. Faslodex
4. Foscavir
5. Merrem
6. Tenormin Injection
7. Xylocaine Injection
8. Zolodex

Following the Effective Date of the CIA, the list of Covered Products for which AstraZeneca is required to report Average Sale Price in accordance with Section III.D of the CIA shall include the above-listed products and all other newly developed injectible products primarily marketed and sold by AstraZeneca to individual medical practitioners/clinics for in-office administration and directly billed by the practitioners/clinics to health care insurers, including Federal health care programs.

* As of February 2003, AstraZeneca no longer makes or sells Elavil Injection. Consequently, AstraZenca may be limited or unable to report Average Sale price for this product in the future.

Attachment B to CIA between AstraZeneca and Office of Inspector General

Audit Workplan for Group Internal Audit (GIA)

As specified more fully below, AstraZeneca shall direct its Group Internal Audit ("GIA") to perform reviews to assist the company in determining the accuracy of Best Price reported for purposes of the Medicaid Drug Rebate Program ("Medicaid Rebate Review"). AstraZeneca shall also direct its GIA to perform reviews to assist the company in assessing and evaluating its systems, processes, policies and practices related to Sales and Marketing ("Sales and Marketing Review").

The GIA shall perform the Medicaid Rebate Review for one randomly selected quarter of each Reporting Period. The GIA shall perform the Sales and Marketing Review annually for each Reporting Period.

A. Medicaid Rebate Review

1. General Description of Medicaid Rebate Review

AstraZeneca's Policies and Procedures (referenced in Section III.B.2 of the CIA) include policies and procedures which the company follows in gathering, calculating and reporting prices for purposes of the Medicaid Drug Rebate Program. The GIA will review a sample of the Best Prices reported to CMS for 50 11–digit NDCs during a randomly selected quarter during the Reporting Period.

2. Medicaid Rebate Review Methodology

The Medicaid Rebate Review shall consist of two parts as follows:

(a) Part One – Review of Samples

At the end of each Reporting Period, the GIA shall randomly select one quarter for review. The GIA will then obtain a listing of all 11-digit NDCs for which Best Price was reported during the quarter under review. The GIA will identify the five 11-digit NDCs for which AstraZeneca paid the largest amount (e.g., total dollars) of rebates to the States under the Medicaid Drug Rebate program in the quarter under review. From the listing, the GIA will also randomly select another 45 11-digit NDCs for review.

For each of the 50 11-digit NDCs included in the Medicaid Rebate Review, the GIA will:

(1) select all prices identified in the AstraZeneca Top Contracts Report and all manual price adjustments within AstraZeneca's government pricing system(s) where an actual sale was recorded in the quarter under review at a price lower than the Best Price reported by AstraZeneca for the NDC for the quarter[1]; and

(2) analyze each of the lower prices and determine, based on AstraZeneca's policies and procedures and the Medicaid Drug Rebate Program requirements, if each price was properly excluded from the determination of Best Price.

(b) Part Two - Additional Investigation

For purposes of additional investigation, an error shall be defined to be any instances in which: 1) contract price terms for the 11-digit NDCs under review which were not appropriately included in or excluded from AstraZeneca's Best Price determination; or 2) the reported Best Price for any 11-digit NDC was incorrectly reported. If the GIA discovers either type of error, then the GIA shall conduct an additional investigation, as may be necessary, to determine the root cause of the error (*e.g.*, review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the error.)

In the event the GIA finds more than one error as defined in the preceding paragraph, the GIA will perform a second Medicaid Rebate Review. The second Medicaid Rebate Review shall consist of the GIA randomly selecting and reviewing (in accordance with the steps outlined in section A.2.a above) an additional five 11-digit NDCs for which AstraZeneca paid Medicaid rebates in the quarter under review.

3. IRO Verification Review

The IRO shall conduct a verification review, which shall evaluate at least 15 of the same 11-digit NDCs reviewed by the GIA. The IRO will independently obtain

1 The review of the AstraZeneca Top Contracts Report and all manual price adjustments will result in a review of all contract prices within AstraZeneca's government pricing system where an actual sale was made at a price lower than the Best Price reported by AstraZeneca for the NDCs for the quarter.

source documentation relating to the 15 11-digit NDCs and will independently conduct the steps outlined contained in section A.2.a above. After the IRO has conducted its verification review and made its independent determinations, it shall: 1) obtain the GIA's findings with regard to each of the 15 11-digit NDCs; 2) compare its own findings to those of the GIA; 3) identify any discrepancies between the two sets of findings; and 4) explain potential reasons for the discrepancies.

If the IRO identifies errors in any of AstraZeneca's findings, the IRO shall conduct a verification review of at least an additional 5 of the 11-digit NDCs reviewed by the GIA. If the IRO identifies any AstraZeneca errors in this additional review, AstraZeneca and the IRO shall notify the OIG to discuss appropriate additional steps to be taken (*e.g.*, additional reviews or a requirement that an IRO, rather than the GIA, conduct all or part of future reviews).

The IRO shall prepare a report based upon its review ("IRO Verification Report"). The IRO Verification Report shall contain, for each NDC reviewed: (i) the IRO's findings; (ii) a detailed description of any discrepancies between the IRO's findings and those of the GIA; and (iii) the IRO's explanation of the possible reasons for the discrepancies. In addition, if the IRO conducted any additional verification review(s) (beyond the initial review of the 15 NDCs), the IRO Verification Report shall contain a detailed description of the results of that review, including the IRO's findings. The IRO Verification Report shall be provided to the OIG.

4. Medicaid Rebate Review Report

The GIA shall annually prepare a report based upon the Medicaid Rebate Review performed. The report shall include the following general elements and information:

(a) Review Objective: A clear statement of the objective(s) intended to be achieved by the review;

(b) Review Protocol: A detailed narrative description of: (i) the sampling unit; (ii) the universe from which the sample was selected; (iii) the procedures performed;

(c) Sources of Data: A full description of documentation (and/or other information) relied upon by the GIA when performing the Medicaid Rebate Review;

(d) a narrative list of the five 11-digit NDCs with the highest rebates paid by AstraZeneca for the quarter under review and the associated Best Price reported by AstraZeneca to CMS and a narrative list of the 45 randomly selected 11-digit NDCs and the associated Best Price reported by AstraZeneca to CMS;

(e) for each 11-digit NDC under review, a list of all contract price terms and the corresponding AstraZeneca customer to which a sale was made at a price lower than the Best Price reported to CMS for that quarter;

(f) for each NDC under review, a description of the steps and the supporting documentation reviewed to determine that each such lower price was appropriately evaluated for purposes of determining the Best Price;

(g) for each NDC under review, a list of any prices not appropriately included in AstraZeneca's Best Price determination for that quarter;

(h) a detailed description of any additional investigation undertaken with regard to any prices that were not accurately included or excluded in AstraZeneca's Best Price determination for the quarter under review and the results of any additional investigation or reviews undertaken with respect to any such price; and

(i) the GIA's recommendations for changes in AstraZeneca's policies and procedures to correct or address any weaknesses or deficiencies uncovered during the review.

B. Sales and Marketing Review

1. General Description of Sales and Marketing Review

The Sales and Marketing Review shall be conducted for three of AstraZeneca's Business Centers annually and shall cover all therapy areas handled by the respective Business Center. The Sales and Marketing review shall consist of two parts: (1) interviews with Pharmaceutical Sales Specialists (PSSs), contract sales representatives, District Sales Managers (DSMs) and other supervisory personnel at the Business Center; and (2) a review of a sample of Control Documents, as defined below, completed by personnel at the Business Center in connection with sales and marketing activities.

AstraZeneca's Policies and Procedures (referenced in section III.B.2 of the CIA), including its Business Policies (hereafter collectively "AstraZeneca's Policies"), set forth certain requirements relating to control type documents used in connection with the following types of activities (hereafter, collectively "Sales and Marketing Related Activities" or "Activities"):

(a) provision of Access Tools (*e.g.*, meals, refreshments, other items) to healthcare professionals (HCPs) or others;

(b) engagement of HCPs, institutions, organizations for contracted services (*e.g.*, consulting, advisory, speaking and other fee-for-service arrangements);

(c) sponsorship of promotional education programs (*e.g.*, speakers programs, convention/symposia exhibits; case study programs, *etc.*);

(d) provision of grants (*e.g.*, educational and other grants);

(e) expenditures for third party advice about reimbursement or claims submissions for Government Reimbursed Products, if any;

(f) provision of customer assistance programs, if any;

(g) provision of drug samples; and

(h) provision of any or all other activities identified in AstraZeneca's Policies and used in connection with Sales and Marketing Activities.

For purposes of this Sales and Marketing Review, "Control Documents" is defined mean all documents associated with the above-referenced Sales and Marketing Related Activities. For instance, Control Documents include Expense Reports, Purchase Orders, and Vendor Invoices, among others.

2. Interviews of Personnel from Business Centers

For each Business Center under review, the GIA shall annually interview at least 5% of the PSSs and their corresponding supervisory DSMs, and shall interview at least three contract sales representatives and one supervisory contract DSM associated with the Business Center. The interviews shall be designed to evaluate the PSSs', the contract sale representatives', and the DSMs' knowledge of and adherence to AstraZeneca's Policies relating to the Sales and Marketing Related

Activities and the extent to which the PSSs and contract sale representatives have engaged in various types of Sales and Marketing Related Activities. The 5% of the PSSs interviewed shall be judgmentally selected from among the PSSs assigned to each Business Center in a manner designed to ensure that PSSs from each therapy area, territory and different experience levels associated with the Business Center are selected for interview.

The GIA shall also identify the therapy area in the applicable Business Center with the highest dollar amounts of budgeted expenditures per PSS for Sales and Marketing Related Activities during the Reporting Period. The GIA shall then conduct interviews with an additional number of PSSs from the identified high-expenditure therapy area. The number of additional PSSs to be interviewed from the high-expenditure therapy area shall be equal to at least 50% of the aggregate number of PSSs selected for the initial interviews (as described above) in the Business Center. The contract sales representatives interviewed shall be randomly selected.

3. GIA Review of Control Documents

For each Reporting Period and for each Business Center, the GIA shall review at least four Expense Reports and other Control Documents, selected from the 12-month period proceeding the review, for each of the PSSs and contract sales representatives selected for interview. At a minimum, GIA shall review 158 Expense Reports annually. In addition, GIA shall review a minimum of 54 non-Expense Report Control Documents associated with the PSSs and contract sales representatives selected for interview. To the extent the GIA cannot identify at least 54 non-Expense Report Control Documents associated with the PSSs and contract sales representatives interviewed, the GIA shall select the 54 non-Expense Report Control Documents for other personnel at the Business Center.

The GIA shall evaluate and review the Control Documents to determine:

(a) whether the Control Documents were completed in accordance with the requirements set forth in the AstraZeneca's Policies;

(b) whether the Control Documents reflect that all required written approvals were obtained in accordance with AstraZeneca's Policies; and

(c) for each Control Document reviewed, whether all supporting documentation (*e.g.*, receipts) and follow-up documentation (*e.g.*, progress and final reports produced in connection with grants) exists in appropriate

files in accordance with AstraZeneca's Policies.

Any Control Document that does not satisfy the criteria set forth above shall be considered an exception and shall be noted by the GIA. The GIA will consider a Control Document to have a Material Error if either of the following is identified:

(a) all the appropriate and required Control Documents do not exist and no corrective action has been taken prior to the GIA review; or

(b) information or data is omitted from key fields in the Control Documents that prevents the GIA from understanding the nature of the expenditure and/or assessing compliance with AstraZeneca's Policies.

4. Additional Review of Material Errors Are Discovered

If the GIA finds any Material Errors, it shall conduct an additional review of the expenditures or activities reflected in the Control Documents at issue. The GIA shall perform this additional review in a manner designed to determine the root cause of the Material Errors. For instance the GIA may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the Material Error.

5. IRO Verification Review

The IRO shall conduct a verification review which shall evaluate least 20% of the same Expense Reports and 20% of the non-Expense Report Control Documents reviewed by the GIA. The IRO will independently obtain source documentation relating to the Control Documents under review and will independently conduct the steps outlined in section B.3 above. After the IRO has conducted its verification review and made its independent determinations, it shall: 1) obtain the GIA's findings with regard to each of the Control Documents; 2) compare its own findings to those of the GIA; 3) identify any discrepancies between the two sets of findings; and 4) explain potential reasons for the discrepancies.

If the IRO identifies errors in any of AstraZeneca's findings, the IRO shall conduct a verification review of at least an additional 10% of the Expense Reports and 10% of the non-Expense Report Control Documents reviewed by the GIA. If the IRO identifies any AstraZeneca errors in this additional review, AstraZeneca and the IRO shall notify the OIG to discuss appropriate additional steps to be taken (*e.g.*, additional reviews or a requirement that an IRO, rather than the GIA, conduct all or part of future reviews).

The IRO shall prepare a report based upon its review ("IRO Verification Report").

The IRO Verification Report shall contain, for each Control Document: (i) the IRO's findings; (ii) a detailed description of any discrepancies between the IRO's findings and those of the GIA; and (iii) the IRO's explanation of the possible reasons for the discrepancies. In addition, if the IRO conducted any additional verification review(s) (beyond the 20% initial review), the IRO Verification Report shall contain a detailed description of the results of that review, including the IRO's findings. The IRO Verification Report shall be provided to the OIG.

6. Sales and Marketing Review Report

The GIA shall annually prepare a report based upon each Sales and Marketing Review performed ("Sales and Marketing Review Report"). Each Sales and Marketing Review Report shall include the following elements/information:

(a) Review Objectives: A clear statement of the objectives intended to be achieved by the review;

(b) Review Protocol: A detailed narrative description of: (i) the sampling units; (ii) the universe from which the sample was selected; and (iii) the procedures performed;

(c) Sources of Data: A full description of the documentation (and/or other information) relied upon by the GIA when performing the Sales and Marketing Review.

(d) a summary of the interviews with the PSSs, contract sales representatives, and DSMs, including the GIA's assessment of: (i) whether the PSSs, contract sales representatives and DSMs received adequate training relating to the Sales and Marketing Activities; (ii) the frequency with which personnel at the Business Center engaged in each type of Activity; and (iii) a detailed description of instances in which the training appeared inadequate and/or the Business Center personnel failed to follow AstraZeneca's Policies.

(e) for each sample unit, the GIA shall state its findings and supporting rationale as to whether: a) the Control Document was completed in accordance with all requirements set forth in the AstraZeneca's Policies; b) the Control Document reflects that all written approvals were obtained in accordance with AstraZeneca's Policies; and c) all supporting documentation and follow-up documentation exists in accordance with AstraZeneca's Policies;

(f) for each sample unit reviewed, the GIA shall identify all exceptions and

Material Errors discovered. For the exceptions, the GIA shall describe in general terms what the errors were. The GIA shall describe those situations when corrective action was taken prior to the GIA review, including a description of the circumstances requiring corrective action and the nature of the corrective action;

(g) if any Material Errors were discovered for any sample unit, the GIA shall describe the Material Error and the additional review procedures it performed, and shall state its findings as to the root cause of the Material Errors; and

(h) the GIA's recommendations for changes in AstraZeneca's Policies in order to correct or address any weaknesses or deficiencies uncovered during the review.

Attachment C to CIA between AstraZeneca and Office of Inspector General

Independent Review Organization (IRO) Reviews

As specified more fully below, AstraZeneca shall retain an Independent Review Organization ("IRO") to perform reviews to assist AstraZeneca in assessing and evaluating its systems, processes, policies and practices related to: 1) the determination of Best Price for purposes of the Medicaid Drug Rebate Program ("Medicaid Rebate Systems Review"); 2) the methodology for calculating Average Sale Price ("Average Sale Price Systems Review"); and 3) its sales and marketing activities ("Sales and Marketing Systems Reviews").

If, during the term of the CIA, there are no material changes in AstraZeneca's systems, processes, policies and practices relating to the determination of Best Price, the calculation of Average Sale Price, or its sales and marketing activities, then the IRO shall perform the Systems Reviews listed above to cover the first and fourth Reporting Periods. If AstraZeneca materially changes its systems, processes, policies or practices, then the IRO shall perform the applicable additional Systems Review(s) covering the Reporting Period(s) in which such changes were made in addition to conducting the Systems Reviews for the first and fourth Reporting Periods.

As specified in section III.E of the CIA, for at least the first two years of the CIA, AstraZeneca shall also retain the IRO to conduct the Average Sale Price Review outlined below in Section D. Each Average Sale Price Review shall cover one randomly-selected quarter of the Reporting Period.

A. Medicaid Rebate Systems Review

1. General Description of Medicaid Rebate Systems Review

For at least the first and fourth Reporting Periods, the IRO shall review and evaluate AstraZeneca's systems, processes, policies and practices associated with the tracking of, gathering of, and appropriate accounting for all data relevant for purposes of determining the Best Prices reported to the Centers for Medicare and Medicaid Services ("CMS").

In general terms, the IRO shall evaluate the following:

(a) the systems, processes, policies, and practices that are in place to track, gather, and appropriately account for contract price

terms that are relevant to the Medicaid Rebate Program. Specifically, this includes a review of:

(1) the processes, policies and procedures used to determine whether contract price terms are appropriately included in the determination of the Medicaid Best Price for any product (this includes: (a) a review of the data or information flow process by which relevant contract price terms are evaluated for purposes of determining the Medicaid Best Price; and (b) a review of any AstraZeneca inquiries to CMS regarding Medicaid Best Price and any responses to those inquiries); and

(2) the computer or other relevant systems used to determine the Medicaid Best Price; and

(b) AstraZeneca's policies and practices for identifying outliers (*i.e.*, reported Best Prices that, according to AstraZeneca's policies, would require further scrutiny), the reasons for any identified outliers, and the identification and correction of any erroneous Best Price reported.

2. Medicaid Rebate Systems Review Report

For each relevant Reporting Period, the IRO shall prepare a report based upon the Medicaid Rebate Systems Review. Each report shall include the following items:

(a) a full description of the systems, processes, policies, and practices in place to track, gather, and appropriately account for those contract price terms that are relevant to the Medicaid Rebate Program, including, but not limited to:

(1) the computer or other relevant system(s) used to determine the Medicaid Best Price;

(2) what information is input into AstraZeneca's relevant computer or other system(s) and whether this information is appropriate and comprehensive;

(3) the system logic or decision rationale used to determine whether relevant contract price terms are included in the determination of the Medicaid Best Price; and

(4) AstraZeneca's policies and practices for identifying outliers, the reasons for any identified outliers, and the identification and correction of any erroneous Best Price reported.

(b) a full description of all documentation, information, and systems reviewed, including but not limited to, a description of AstraZeneca's inquiries to CMS regarding Best Price, any responses to those inquiries, and a summary of interviews with personnel (if any interviews were conducted); and

(c) observations, findings, and recommendations on possible improvements to AstraZeneca's systems, processes, policies, and practices, including the IRO's assessment of whether AstraZeneca's systems, processes, policies and practices result in the inclusion of appropriate and relevant contract price terms in the determination of the Medicaid Best Price.

B. Average Sale Price Systems Review

1. General Description of Average Sale Price Systems Review

For at least the first and fourth Reporting Periods, the IRO shall review and evaluate AstraZeneca's systems, processes, policies and practices associated with the tracking of, gathering of, and appropriate accounting for all data relevant for purposes of calculating the Average Sale Prices reported pursuant Section III.D of the CIA.

In general terms, the IRO shall evaluate the following:

(a) the systems, processes, policies, and practices that are in place to track, gather, and appropriately account for price terms that are relevant for purposes of the Average Sale Price. Specifically, this includes a review of:

(1) the process, policies, and procedures used to determine whether particular transactions reflecting final sales prices are included in or excluded from the calculation of the Average Sale Price for any product (this includes: (a) a review of the decision rationale by which sales to certain types of customers are included in or excluded from the calculation of Average Sale Price; (b) a review of the decision rationale by which certain transactions are included in or excluded from the calculation of Average Sale Price; and (c) the relevant data or information flow process by which relevant price terms are evaluated for purposes of determining the Average Sale Price);

(2) the computer or other relevant system(s) used to calculate the Average Sale Prices; and

(b) AstraZeneca's policies and practices for identifying outliers (*i.e.*, reported Average Sale Prices that, according to AstraZeneca's policies, require further scrutiny), the reasons for any identified outliers, and the identification and correction of any erroneous Average Sale Price reported.

2. Average Sale Price Systems Review Report

For each relevant Reporting Period, the IRO shall prepare a report based upon the Average Sale Price Systems Review. Each report shall include the following items:

(a) a full description of the systems, processes, policies, and practices in place to track, gather, and appropriately account for price terms relevant for purposes of the Average Sale Price including, but not limited to:

(1) the computer or other relevant systems used to calculate the Average Sale Price;

(2) what information is input into AstraZeneca's relevant computer or other system(s) and whether this information is appropriate and comprehensive;

(3) the system logic or decision rationale used to determine whether certain transactions are included in or excluded from the calculation of the Average Sale Price; and

(4) AstraZeneca's policies and practices of identifying outliers, the reasons for any identified outliers, and the identification and correction of any erroneous Average Sale Price reported.

(b) observations, findings, and recommendations on possible improvements to AstraZeneca's systems, processes, policies, and practices, including the IRO's assessment of whether AstraZeneca's systems, processes, policies and practices result in the inclusion of appropriate and relevant price terms in the determination of the Average Sale Price.

C. Sales and Marketing Systems Review

1. General Description of Sales and Marketing Systems Review

For at least the first and fourth Reporting Periods, the IRO shall review AstraZeneca's systems, processes, policies and practices associated with the following types of activities (hereafter collectively "Sales and Marketing Related Activities" or "Activities"):

a) provision of Access Tools (*e.g.*, meals, refreshments, other items) to healthcare professionals (HCPs) or others;
b) engagement of HCPs, institutions, organizations for contracted services (*e.g.*, consulting, advisory, speaking and other fee-for-service arrangements);
c) sponsorship of promotional education programs (*e.g.*, speakers programs,

convention/symposia exhibits; case study programs, *etc.*);
d) provision of grants (*e.g.*, educational and other grants);
e) expenditures for third party advice about reimbursement or claims submissions for Government Reimbursed Products, if any;
f) provision of gifts, if any;
h) provision of customer assistance programs, if any;
i) provision of debt forgiveness, debt reduction, or other like assistance to customers, if any; and
j) provision of drug samples.

For each of the Sales and Marketing Related Activities, the IRO shall determine the following:

(a) whether AstraZeneca has instituted control and accountability systems (*e.g.*, documentation and approval requirements, tracking mechanisms) and written policies regarding the Activity;
(b) whether the control and accountability systems and the written policies are adequate and appropriate;
(c) the manner in which the control and accountability systems and the written policies are made known or disseminated within AstraZeneca;
(d) what disciplinary measures AstraZeneca has established for failure to comply with the control and accountability systems and written policies; and
(e) the number of instances and the circumstances in which AstraZeneca took disciplinary actions for failure to comply with the systems and policies.

2. Sales and Marketing Systems Review Report

For each relevant Reporting Period, the IRO shall prepare a report based upon the Sales and Marketing Systems Review. Each report shall include the following items for each of the Sales and Marketing Related Activities:

(a) a description of the documentation reviewed and any personnel interviewed;
(b) a general description of AstraZeneca's control and accountability systems and written policies and actual practices and the IRO's

assessment about their adequacy and appropriateness;
(c) a description of the manner in which the control and accountability systems and written policies are disseminated or made known within AstraZeneca;
(d) a general description of the disciplinary measures AstraZeneca has established for failure to comply with the control and accountability systems and written policies;
(e) a description of the number of instances and a description of the circumstances in which AstraZeneca undertook disciplinary actions for failure to comply with the systems and policies;
(f) the findings and supporting rationale regarding any weaknesses in AstraZeneca's sales and marketing related systems, policies and practices; and
(g) any recommendations to improve any of AstraZeneca's sales and marketing related systems, policies or practices.

D. Average Sale Price Review

1. General Description of Average Sale Price Review

Section III.D of the CIA requires AstraZeneca to calculate and report Average Sale Prices for Covered Products. The IRO shall randomly select five 11-digit NDCs for which Average Sale Prices were reported during the quarter of the Reporting Period under review. The IRO shall then randomly select 50 transactions (defined to be final sale prices) associated with each of the five 11-digit NDCs. This review shall determine, in accordance with AstraZeneca's policies and procedures and the CIA requirements, whether: 1) each transaction is supported by source documentation; and 2) whether each transaction has been appropriately considered (*i.e.*, included or excluded) for purposes of determining an Average Sale Price for the 11-digit NDC under review.

2. Average Sales Price Review Methodology

The Average Sale Price Review shall consist of two parts as follows:

(a) Part One – Review of Samples

At the end of each Reporting Period, the IRO shall randomly select one quarter for review. The IRO will then randomly select 5 11-digit NDCs for which Average Sale Price was reported during the quarter under review. From that listing, the IRO will randomly select for review 50 transactions associated with each of the five 11-digit NDCs.

For each of the five 11-digit NDCs included in the Average Sales Price Review, the IRO will:

(1) obtain information about all transactions reflected anywhere in AstraZeneca's systems relating to the calculation of Average Sale Price for the 11-digit NDC under review; and

(2) for each of the five 11-digit NDCs, the IRO will review a sample of 50 randomly selected transactions to determine whether: 1) each transaction is supported by source documentation; and 2) each transaction was properly included in or excluded from the calculation of Average Sale Price.

(b) Part Two - Additional Investigation

For purposes of additional investigation, an error shall be defined to be any transaction that was: 1) not supported by source documentation; or 2) not appropriately included in or excluded from AstraZeneca's Average Sale Price calculation. If the IRO discovers either type of error, then the IRO shall conduct an additional investigation (*e.g.*, conduct interviews and/or review additional documentation) as may be necessary to determine the root cause of the error.

3. Average Sale Price Review Report

The IRO shall annually prepare a report based upon the Average Sale Price Review performed. The report shall include the following general elements and information:

(a) Review Objectives: A clear statement of the objective(s) intended to be achieved by the review;

(b) Review Protocol: A detailed narrative description of: (i) the sampling unit; (ii) the universe from which the sample was selected; (iii) the procedures performed;

(c) Sources of Data: A full description of documentation (and/or other information) relied upon by the IRO when performing the Average Sale Price Review.

(d) a narrative list of the five 11-digit NDCs for which AstraZeneca reported Average Sale Price for the quarter under review and the associated Average Sale Price reported for each;

(e) for each NDC under review, a list of all transactions reviewed and a description of all documentation supporting the transaction;

(f) for each NDC under review, a description of the steps and the supporting documentation reviewed to determine that each transaction was appropriately included or excluded for purposes of determining the Average Sale Price;

(g) for each NDC under review, a list of any transactions not appropriately included in or excluded from AstraZeneca's Average Sale Price determination for that quarter;

(h) a detailed description of any additional investigation undertaken with regard to any identified error and the results of any additional investigation or reviews undertaken with respect to any such error; and

(i) the IRO's recommendations for changes in

AstraZeneca's policies and procedures to correct or address any weaknesses or deficiencies uncovered during the review.